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## INTRODUCTION

When patients choose a treatment plan in a manner consistent with their values, preferences, and individual decision making style, they generally have better outcomes<sup>(1,2)</sup> in part because patient involvement also improves the quality of therapeutic decisions.<sup>(3,4)</sup> Greater involvement may also optimize the decision-making process by which treatments are chosen thereby reducing untoward decision outcomes such as disappointment, regret, or depression.

There has been increasing interest in developing techniques to help cancer patients choose between therapies in ways that are consistent with their personal preferences<sup>(5)</sup> while adhering to procedures that improve the quality of the decision-making process. Components of decision-making behavior such as information seeking, personal control, participation, and risk assessment have been implicated in providing good psychological outcomes. But there is little research to suggest how tailored decision support will influence relevant outcomes such as patient satisfaction, psychological well being, and quality of life. An expedient and theoretically sound decision intervention is to provide the structured support of an expert system built on systematic research concerning individual styles of decision behavior.<sup>(6,7)</sup> The purpose of this project is to design and build a computer-assisted prototype of an individualized decision support system, called *Choices*, to assist women newly diagnosed with breast cancer in making stressful treatment decisions in a non-threatening, self-paced, and individualized manner.

Using a multimedia CD-ROM format, *Choices* will provide an innovative approach to personalized decision making by incorporating unique features that currently are not available in existing programs. The vision of the *Choices* program is a joint venture among a multidisciplinary group of scientists at the University of Michigan who bring their respective expertise to the complex problem of helping patients make effective decisions under stressful and threatening circumstances. Specifically, *Choices* has the following unique features: (1) the program is designed to be user-friendly and comfortable for women of all ages and education levels, (2) an assessment of the decision maker's personal decision style will be used to set the structure of the program,<sup>(6,7,8)</sup> (3) the program will consider the cognitive demands of the decision maker in this health care context by assessing the capacity for directed attention (CDA),<sup>(9-12)</sup> (4) it goes beyond eliciting personal values and preferences by providing solutions to common decision failures,<sup>(13)</sup> and (5) provides an opportunity for pre-decision rehearsal of different options to avoid unexpected decision outcomes or negative emotional responses.

Patient participation in clinical decision making is a focus of growing attention within the scientific and medical communities as well as public media and consumer groups.<sup>(3,14)</sup> The societal shift toward deliberative models of patient-provider interaction<sup>(15)</sup> is most evident in the diagnosis of breast cancer, where the selection of a treatment rests upon a woman's personal values and preferences. Because there are ever-increasing constraints placed upon the time providers can devote to decision counseling, there are advantages to changing the therapy-decision process. Interaction with health care providers is time consuming and frequently biased by the experience and preferences of the provider<sup>(16)</sup>. Geographic variations in treatment also exist.<sup>(17, 18)</sup> An expedient and theoretically sound decision intervention is to provide the structured support of an expert system built on systematic research of real-world decision making.<sup>(7,8)</sup>

In recent years there have been important steps taken to capture contemporary technologies such as video and computer programs to aid patients in making cancer treatment decisions. <sup>(19,20,21)</sup> We are taking this work further by developing an interactive and individualized decision support program for women with breast cancer. The program, titled *Choices*, represents our collective desire to help women through the treatment decision process by prescribing a series of action steps that help visualize the decision problem in smaller and manageable segments and to help communicate individual needs and preferences to doctors, family, and friends.

Existing programs have been designed for patient consumers who are high information seekers and have a need to be involved in treatment decision making. In contrast, *Choices* is designed for a variety of decision-making styles, from the woman who wishes to know how to select a physician to make the decision for her to one who wants the latest scientific information so she can decide for herself. Also, *Choices* will address the unique needs of the 48% of the breast cancer population over the age of 65 years <sup>(22)</sup> who are more likely to accept a doctor's suggestions without question <sup>(23, 24)</sup> yet tend to reject potentially effective therapy because of misinformation or lack of social support. <sup>(25)</sup>

The project brings an innovative approach to clinical decision-making activities by placing state-of-the-art interactive computer technologies in the hands of women facing treatment for breast cancer. By providing an individualized approach to treatment decisions we will be able to determine in future studies if decision support influences patient satisfaction with treatment and if satisfaction, in turn, influences psychological well being. Ultimately, our objective is to enhance the quality of life of women facing breast cancer treatment by providing quality decision support that is effective, practical, and empowering.

Primary treatment for early stage breast cancer involves choosing between a modified radical mastectomy (with or without breast reconstruction) and breast conservation therapy (i.e., lumpectomy/segmentectomy, axillary lymph node dissection, and postoperative radiation therapy). After primary treatment, some must decide whether to accept adjuvant chemotherapy or hormonal therapy. Facing such decisions creates tremendous turmoil and distress. Women are overwhelmed by the responsibility of making such choices and do not always have the physical, emotional, or cognitive resources to be effective decision makers. <sup>(13)</sup>

There is preliminary evidence <sup>(6, 26)</sup> to suggest that patients' participation in treatment decision making influences their psychological well-being. Components of decision-making behavior such as information seeking, personal control, participation, and risk assessment have been implicated in providing good psychological outcomes. <sup>(27)</sup> But there is little research to suggest how tailored decision support will influence patient satisfaction with treatment. Further, there is even less research to determine if there is a relationship between patient decision-making behavior and psychological well being following treatment.

We believe it is practical to resolve several issues that are critical to the development of a fully operational system. First is to develop decision algorithms tailored to each decision style. Second, we have identified the key values that influence particular treatment decisions. Other programs have components of a traditional value assessment, but they have not sufficiently addressed the relation between values and actual decision behavior. Third, we are providing the opportunity to visualize a range of possible outcomes to help women avoid common decision errors. Fourth, we are developing unique communication modules that will support information seeking as well as information sharing to



help script letters to employers, health care professionals, or insurance companies concerning the treatment decision. Finding ways to facilitate communication may provide social and economic support to women so they are better able to follow through with their preferred treatment.

**Specific Aims** of this project are to assist women and their families: (1) make active decisions about breast cancer treatment that reflect their goals, values, and personal decision making style, (2) in making more informed decisions by providing readily accessible information, and (3) avoid common decision errors by rehearsing various outcome scenarios and making the necessary corrections to increase satisfaction with the choice.

**Decision-Making Behavior.** Consistent with Pierce's earlier descriptive work, <sup>(6,7)</sup> decision behavior can be classified into descriptive categories called decision styles. In order of complexity, the three decision styles are termed Deferrer, Delayer, and Deliberator. The Deferrer is immediately attracted to the alternative that is most salient, reports no conflict, does not engage in either deliberation or information seeking, and tends to avoid risk. Deferrers frequently select the alternative recommended by the physician, deferring to the "expert's judgment". The Delayer, in contrast, is attracted to more than one alternative and experiences minimal conflict as she vacillates between them without being able to arrive at a satisfactory choice of treatment. The Deliberator considers numerous alternatives and decomposes, or breaks down, each alternative into smaller parts for independent consideration. In contrast to the other decision styles, Deliberators tend to be more risk-seeking and are willing to tolerate both ambiguity and uncertainty throughout their extensive information-seeking activities. The three styles differ with respect to the type and amount of information that is considered, depending on how much responsibility the patient has for the choice, whether the patient prefers to defer to others, and what deliberative process is used for combining and organizing information

**Decision Maker's Cognitive Capacity.** One factor that can significantly affect decision making is the capacity to concentrate or to direct attention. Concentration, or the capacity to direct attention (CDA), refers to the ability to focus on intended activity by blocking or inhibiting competing stimuli during goal-directed or purposeful activity. <sup>(28-31)</sup> CD also provides inhibitory control for many higher cognitive or "executive" functions, <sup>(32,33)</sup> i.e., formulating goals, deciding, planning, initiating, and carrying out tasks. A goal-directed activity such as deciding on breast cancer treatment would require sustained focus and control of interference or distractions. Sustaining CDA however, requires continuous application of mental or neural inhibitory effort. Thus, intense use of directed attention can lead to attentional fatigue, resulting in reduced effectiveness in goal-directed activity such as treatment decision-making. <sup>(28, 34, 35)</sup> Cimprich (Consultant) has postulated that in response to intense and/or prolonged attentional demands or requirements, women with breast cancer are likely to develop attentional fatigue, manifested as a measurable decline in CDA with reduced effectiveness in purposeful functioning. Women with breast cancer are confronted with multiple attentional requirements - informational, affective, and behavioral - beginning with the suspicion of cancer and confirmation of the disease. <sup>(35,36)</sup> Previous research by Cimprich <sup>(10-12)</sup> has shown that women treated for breast cancer may experience significant attentional impairment. Although attentional fatigue can reduce effectiveness of cognitive functioning, there has been no research on the possible influence of attentional fatigue on decision-making behaviors in women newly diagnosed with breast cancer.

**Common Decision Failures.** Expectations of future emotional states include one's anticipated regret, relief, worry, depression, or satisfaction following the decision. These emotional states will be assessed as well as anticipation that an emotional state, or other factors such as social support, will interfere with

quality of life. A process of comparing what happened with what might have happened frequently follows stressful decisions and the experience of their consequences.<sup>(37)</sup> This act of comparison represents a cognitive basis for the emotion of regret. Although the rationality of regret following a well-made decision is questionable, there is no question that it is rational to consider the degree of regret one might experience before a decision is made.<sup>(37-39)</sup> We propose to see whether it is possible for people to anticipate the amount of regret they would experience with breast cancer treatment. If so, we will then be in a position to find out whether women make a decision they can better live with when they explicitly take the anticipation of regret into consideration.

The project holds both a scientific as well as a clinical objective. Scientifically, the prototype has hypothesis-testing value because the program will provide a process tracing of the individual's decision-making experience by mapping decision processes. This is done by quantifying the length of time spent in each module and identifying avoided information (sources of bias), navigation from module to module, and the frequency of revisits to modules. Such data can be useful for theory building and testing regarding real-world decision behavior as compared to normative modes prescribing optimal or rational decision behavior in such contexts.<sup>(8)</sup> Ultimately, process tracing evaluation will be incorporated into the full program as an unobtrusive measure of the cognitive processes involved in making this treatment choice under these real-world constraints.

Clinically, the objective is to develop and deliver individualized strategies for helping women make stressful and irrevocable treatment decisions using advanced technologies in a user-friendly and supportive format while addressing the executive functions necessary for sound judgment and quality decision making under threatening and time-constrained circumstances. The prototype development process will address the need to enhance and in some cases, restore, cognitive processes necessary for sound decision making.

## BODY

**Study Design Overview.** The proposal aims to develop, field test, and provide ongoing evaluation of a patient decision support system based on a product development approach. At the conclusion of the 2-year design and development stage we will have a model system available for further research and evaluation with a clinical sample.

**Prototype Development Process.** Development of a testable prototype is an iterative process among teams including: (1) an engineering panel including programmers and systems expert, (2) a design and media panel, (3) an advisory panel comprising domain experts in breast cancer and decision science as well as breast cancer survivors, and (4) a laboratory test panel of non-patients. The Engineering Team is directed and supervised by Co-Investigator Andrew Crawford, an Industrial Engineer who is responsible for developing the computer program software. Our Design and Media Panel includes a senior technical writer and graphic artist and is responsible for writing and editing text that is clear and as non-threatening as possible. An Advisory Panel is assembled to include domain experts in breast cancer (members of the Comprehensive Cancer Center) and decision making (members of the Michigan Decision Behavior Consortium) as well as women who are cancer survivors and willing to participate in the development of this project. This panel meets with project staff periodically to review our detailed program plans during development. We want to assure that our direction fits with our stated goals and that the work will be highly beneficial to breast cancer patients.



The panel is also part of the alpha testing of modules to provide feedback before they are put into laboratory testing. A Laboratory Test Panel is being formed and will consist of age-relevant women subjects who will test components of the prototype.

The program is being developed using MacroMedia Director on the Macintosh platform. MacroMedia Director is deemed the best commercial multimedia program available. It contains a simple development shell that is capable of producing seamless multimedia sessions. The program structure will be designed in a manner that is interactive, inviting, and nonthreatening to the novice user. A major design objective is to support CDA with particular focus on clarity, vividness, readability, pacing, relevance, and economy of information. Color and sound is used to help the patient feel comfortable and reduce the demands of the task. All images and text are simple, large, and easy to understand. A preliminary design model addresses the key unique features of this proposal which includes: (1) an assessment of personal decision style, (2) attention to the cognitive demands (CDA) of the decision maker with respect to this unique and stressful decision, and (3) an opportunity for pre-decision rehearsal to avoid common decision errors.

The *Choices* program is tentatively designed along the following line of reasoning. Our assumption is that women facing this treatment decision have preferences about the treatment options as well as about how they want to go about making the choice and their level of desired participation in the decision-making process. We want to provide support that is consistent with a patient's style; some may wish to be actively involved, while others may wish to defer to an expert. We also recognize that this is a very distressing time for women and they may not have the emotional or cognitive capacity to address this difficult task. The program begins with a *Readiness Assessment Module*, which builds on the work of Dr. Cimprich and determines if the decision maker has the capacity to direct the attention necessary to engage in the decision independent of her desire to be involved or not. This module provides feedback about whether the woman is "ready" to tackle the complex problem ahead of her. If she does not show the capacity to move on, recommendations are provided to help her get ready such as: (1) getting rest, (2) engaging in a restorative activity, <sup>(12)</sup> and/or 3) engaging the aid of an advocate to help her monitor the information in the program and help keep her focused. If it is determined she is ready, the program will move her to the *Decision Assessment Module* where her decision style will be determined using Pierce's 16-item instrument, <sup>(8)</sup> which classifies decision makers as Deferrers, Delayers, or Deliberators. This instrument was developed on the empirical findings of the original work of Dr. Pierce, <sup>(6,7)</sup> and extended through a series of small pilot projects and ultimately tested on a sample of 483 women seeking breast cancer screening. Through a series of exploratory and confirmatory factor analyses, four separate factors were identified, providing excellent fit using a structural equation modeling approach <sup>(39)</sup> using the statistical program EQS-Windows. The four factors are Deferring Responsibility, Avoidance, Information, and Deliberation. The four-factor higher-order model tested included a single higher-order factor to represent all four of the decision style factors. Findings of the analysis indicate that the four factors are theoretically important in determining a woman's decision style as either a Deferrer, a Delayer or a Deliberator. This component of the program is complete and provides a mechanism for scoring the instrument to determine the decision making style as well as providing feedback to the decision maker and any other support or professional person she would like to share the information with.

A *Validation and Reconsideration Component* follows each assessment phase where the decision maker receives feedback and is provided an opportunity to reconsider. Following feedback concerning one's decision style we ask the decision maker to identify what is positive and negative about this approach and point out the implications of each style and possible decision errors inherent in

each style. Most people will benefit from an exploration of the benefits (positive aspects), costs (negative aspects), and risks (possible negatives) of each way of approaching a decision problem. This validation and reconsideration component does not attempt to change an individual's style, rather, it informs them of the issues inherent in each style that would be helpful to consider.

A unique feature of the system is the provision of built-in checks for potential decision errors or failures. By designing a support system that "fixes" the flaws in the approaches a given patient is likely to apply, such as providing structured support or compensation for weaknesses in the patient's natural means of deciding, the quality of the decision can be improved. There are a number of dimensions, but two are most relevant in this context. The first entails that a decision can be deficient in the sense that the decision maker selects an option whose aggregate outcomes are worse than those of a competing option. By "aggregate outcomes" we mean the entire panoply of outcomes the decision maker eventually experiences after an option is selected. In this instance, they would include various health, social, economic, and psychologic outcomes of the selected treatment.

The second quality criterion concerns "process costs", the various costs entailed in arriving at the decision. Thus, even if two decision makers choose the same therapy, the decision of one might be superior to the other because she incurred fewer costs arriving at the decision. Among common decision costs are time, money, and "aggravation." Most of the style issues implicate process costs. For instance, a patient who is forced to decide in a manner incompatible with her preferred style makes a "bad" decision in the sense that she is highly aggravated by the process. We could, in principle, provide a valuable service by reducing such costs. Some of the literature on patient involvement in decision making can be conceptualized this way as well. For example, for some patients, at least, aggravation can lead to stress that ultimately affects the patient's health and well-being. <sup>(21,41,42)</sup>

In our collective experience, almost every analytic decision requires resolution of key issues. Issues related to possibilities, realization, and value are most pertinent to our project. The *possibilities issue* asks: "What are the potential consequences of the alternatives that I would care about?" The decision maker, particularly in a breast care situation, which she has never encountered before, could easily make a bad decision because she resolves this issue badly, failing to grasp the potential consequences. Our aid could be tremendously helpful by (a) evaluating the patient's awareness of these possibilities and (b) correcting misconceptions and omissions.

The *realization issue* asks, "Which of the potential consequences would in fact be realized if I were to pursue the given options?" In essence, this is a judgment question, and expert medical and nursing advice is most pertinent here. A "good" decision in this respect would be predicated on accurate assessments of, for instance, the individual patient's chances of experiencing various consequences, such as body image changes or depression ("good" is defined from the patient's perspective <sup>(5)</sup>).

The *value issue* asks, "Suppose various consequences did occur. How would I feel about them - positive, or negative, or indifferent?" The valuation assessment module of the program implicates this issue. For instance, in traditional decision analysis, one simply elicits the client's value/decision functions and, as long as those assessments don't contradict one another, the analyst just moves on. An innovative feature of this proposal asks, "How and why might the person's self-assessments be "wrong"?" For example, the patient thinks that something is no big deal but discovers that it is, or vice

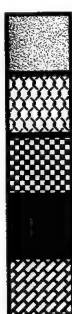
versa. Thus, our program will test the validity of the patient's assessments and, when validity is questionable, help her to get closer to "the truth."

A *Value Assessment Module* has been designed to generate a list of possible outcomes for the treatments being considered. Once the list is complete, the decision maker is asked how she feels about these possible outcomes as well as her assessment of the chances these things will actually occur. This activity is followed by a validation and reassessment loop as the previous modules have done. This component is built on the work of Dr. Yates (Co-Investigator) who has done extensive work in this area<sup>(13,27)</sup>. He has pointed out that value assessments can go awry for two basic reasons: (1) an individual thinks he/she will value something one way which is in fact different from the way he or she actually feels (reactivity error), or (2) when a person thinks that a particular experience entails other experiences when in fact it does not (entailment errors).<sup>(27)</sup> Since breast cancer treatment decision making is a novel task for most women, they do not really know how they will react unless encouraged to consider this possibility before the decision is implemented. An additional component has been added to the original proposal and this critical step involves aggregating the individual assessment of the decision maker's style, preferences, and values and from this information devising a tailored action plan. Such plans include such activities as: (1) seeking additional and pertinent information, (2) obtaining a second opinion, (3) identifying areas the decision maker may wish to devote her effort to clarify how she feels (e.g., loss of a breast or undergoing extensive reconstruction), and (4) effective ways to interact with medical professionals to optimize the decision making process.

In summary, the proposed *Choices* program offers an innovative plan to build on existing technologies in consumer health education by addressing the unique issues concerning individualized assessment of decision style, the explicit consideration of attentional capacity in stressful-decision-making behavior, and incorporating techniques to forestall common decision errors.

**Statement of Work**

	Year 1 1997				Year 2 1998				Year 3 1999	
Quarter	1	2	3	4	1	2	3	4	1	2
<b>PROTOTYPE DEVELOPMENT</b>										
Assemble advisory and technical panels										
Purchase equipment & supplies										
Develop systems plan for prototype										
Write and edit text for program modules										
Programming										
Laboratory testing of components <sup>1</sup>										
Review of prototype by advisory panel(s)										
Preliminary field testing										
Prepare Interim and Final reports										
Prepare Papers for Presentation and Publication										



= Project Staff

= Design and Media Panel

= Engineering Panel

= Laboratory Test Panel

= Advisory Panel

<sup>1</sup>This section has been revised from the original proposal to expand the laboratory testing phase.

## CONCLUSIONS

As a product development project, we do not have results to report but rather progress toward the design and testing of the decision support prototype. To date the project is on schedule despite the fact we have added components to the program that were not originally proposed. For example, two versions of a value assessment component have been developed because of the lack of empirical evidence supporting a single elicitation procedure. These alternate versions will soon be tested to determine which results in the most accurate representation of the individual's value structure as well as the method that most effectively conserves cognitive capacity.

The development of the decision support system has raised critical issues concerning which tasks might be best addressed in a stand alone CD-ROM format and which require the support of a trained decision counselor. As the alpha testing phase begins later in the Fall of 1998, we expect to clarify those tasks that are most suitably conducted using computer support and those that require human interaction. This is an important area to pursue as there is currently little empirical evidence in this domain of decision science.

The original vision of the project was to provide a user-friendly decision support platform to assist women in making breast cancer treatment decision. As we have developed the program and shared the prototype with others, the response has been extremely positive and enthusiastic. There are multiple implications of this project including: (1) improving the quality of the decision making process under stressful circumstances, (2) reducing untoward post decision outcomes including regret, and (3) empowering the patient/provider relationship to choose a treatment that is reflective of the decision maker's values, preferences, and expectations for the future.

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